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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/784,597	10/12/2004	Joseph P. Errico	SPINE 3.0-437 CIPCIPCI	8309
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SPINE MP LERNER, DAVID, et al. 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090			PELLEGRINO, BRIAN E	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/784,597	Applicant(s) ERRICO ET AL.	
	Examiner Brian E. Pellegrino	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 and 15-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 and 15-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments, see pages 8-10, filed 5/5/09, with respect to the 112 2nd paragraph rejection have been fully considered and are persuasive since the claims have been amended to clarify the location. The 112 2nd paragraph rejection of all claims has been withdrawn. Applicant's arguments with respect to the Paponneau rejection have been fully considered but they are not persuasive. Applicant argues that Paponneau discloses pivotably coupling the baseplates to the trunk and that the claimed invention does not move at all. The Examiner is entitled to give terms in a claim its plain meaning as interpreted by one of ordinary skill in the art. It is noted that the specification must clearly set forth the definition explicitly and with reasonable clarity, deliberateness, and precision. Exemplification is not an explicit definition. Even explicit definitions can be subject to varying interpretations. See *Teleflex, Inc. v. Ficosa North America Corp.*, 63 USPQ2d 1374, 1381 (Fed. Cir. 2002), *Rexnord Corp. v. Laitram Corp.*, 60 USPQ2d 1851, 1854 (Fed. Cir. 2001) and MPEP 2111.01. Applicants fail to establish how an "immovably **coupled**" baseplate to a trunk is accomplished let alone point out where it is even illustrated. Therefore the Examiner is giving this recitation the broadest reasonable interpretation. First it must be noted that to "**couple**" is to join. Paponneau clearly shows the baseplates are coupled to the trunk and Applicants even agree as admitted on page 11. Once the baseplates are coupled to the

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trunk they cannot rotate and cannot be detached since the plates are snapped onto the trunk. Thus, they are immovably coupled.

Specification

The disclosure is objected to because of the following informalities: the amendment to the specification of 1/18/08 to correct the continuity has been entered. However, the additional use of titles for applications and abbreviations of applications i.e. "the '081" patent will not be permitted and will not be included in the specification. According to MPEP, 35 U.S.C. 120 only requires **continuity** to be established by the relationship to a prior application with **its number and/ or patent** if it has issued. An appropriate corrected version is required.

Additionally, the reference to add the above, noted, prior-filed applications in the first sentence of the specification on page one following the title is not acceptable as drafted since it has improperly incorporated by reference the prior-filed applications. An incorporation by reference statement added after an application's filing date is not effective because no new matter can be added to an application after its filing date (see 35 U.S.C. § 132(a)). If an incorporation by reference statement is included in an amendment to the specification to add a benefit claim under 35 U.S.C. § 120 after the filing date of the application, the amendment would not be proper. When a benefit claim under 35 U.S.C. § 120 is submitted after the filing of an application, the reference to the

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prior application cannot include an incorporation by reference statement of the prior application. See *Dart Industries v. Banner*, 636 F.2d 684, 207 USPQ 273 (C.A.D.C. 1980). Note MPEP §§ 201.06(c) and 608.04(b). To be clear to Applicant, since the proper relationship to prior applications was not established upon the filing of the current application, the only relationship that can be assumed is priority as a continuation with the subject matter of the current application only being supported by the earliest date of the parent having that subject matter. To then amend the specification to claim continuation-in-part to prior applications and incorporate by reference the subject matter of each of those applications not included in this application is not permissible.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1,3-7,10-12,18-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Paponneau (2003/176925). Fig. 1 shows apparatus for preparing an intervertebral space with two baseplates **24**, **26** and are immovably coupled via cylindrical trunk **22**. Fig. 2 shows clips to “immovably couple” the plates together. Since the plates will not rotate once connected to the trunk and can not separate from the trunk they are “immovably coupled” to the trunk. Fig. 3 show the baseplates include a plurality of engagement holes **64A-C**, **66A-C** extending into the baseplate to a direction substantially perpendicular to the plurality of surgical approach directions. Regarding claim 4, Fig. 8A illustrates the plates can be angled with respect to one another and can

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be approximately 15 degrees. Regarding claims 6,7, since there is space about the trunk because it is smaller in width than the plates it forms a "groove" and is thus annular. With respect to claims 10,11, the apparatus is fully capable of being used in any of the surgical approach directions, such as an anterior or anterior-lateral approach. Regarding claims 12,20 since the baseplates have a thickness, it can be said that there is a surface facing an anterior surgical approach direction and two anterior-laterally facing surfaces extending perpendicular to the anterior-lateral approach.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Paponneau (2003/176925) in view of Kuras (6607558). Paponneau is explained supra. However, Paponneau fails to disclose the contour of the outward facing surface of the baseplates to have a contour of a dome. Kuras teaches (Figs. 1-3) a spinal device that has two upper and lower support structures **20, 40** with convex or domed outward facing surfaces **22, 42** for engaging the disc space. It would have been obvious to one of ordinary skill in the art to use a convex or domed contour as taught by Kuras for the baseplates of Paponneau such that it more closely matches the contour of the vertebrae surface that the apparatus is to engage.

Claims 8, 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paponneau (2003/176925) in view of Baumgartner (5370697). Paponneau is explained

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supra. However, Paponneau fails to disclose the floor of the groove is narrower than an opening of the groove or the groove floor being ridged. Baumgartner teaches (Fig. 1a) a spinal device that has two upper and lower support structures **2, 3** with an inner “groove” having a floor with ridge **21** for holding the trunk component **5**. Baumgartner additionally teaches (col. 2, line 58) a narrower profile for the floor of the “groove”. It would have been obvious to one of ordinary skill in the art to modify the baseplates and use a ridged floor as taught by Baumgartner in the baseplates of Paponneau such that it more effectively retains the trunk between the two baseplates.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Paponneau (2003/176925) in view of Berry (5895428). Paponneau is explained supra. However, Paponneau fails to disclose the anterior facing surface of the baseplates is angled at a degree of approximately 33.4. Berry teaches (Figs. 2,4) a baseplate that has an angled anterior facing surface. However, Berry does not teach the explicit angle. It would have been obvious to one of ordinary skill in the art to modify the anterior facing surface to be angled as taught by Berry on the baseplates of Paponneau such that it provides more stability in the central region of the apparatus containing the trunk.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Paponneau (2003/176925) in view of Nishijima et al. (5899941). Paponneau is explained supra. However, Paponneau fails to disclose the apparatus baseplates having different width and depth dimensions. Nishijima et al. teach (Figs. 3a,3b) apparatus for a spinal disc space with the upper and lower baseplates **2, 3** with different width and depth dimensions. Nishijima also teaches that one of the baseplates is to

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have the central structure integral with the plate, col. 1, lines 51-53. It would have been obvious to one of ordinary skill in the art to simplify the apparatus for the spinal space by making an integral trunk with the baseplate as taught by Nishijima et al. for the apparatus of Paponneau such that it reduces the cost of manufacturing by lowering the number of components that would have to be molded.

Claims 16,17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paponneau (2003/176925) in view of Nishijima et al. (5899941) as applied to claim 15 above, and further in view of Boriani et al. (6159211). Paponneau as modified by Nishijima et al. is explained supra. However, Paponneau in view of Nishijima et al. do not explicitly disclose the width dimension in a range up to 40mm. Boriani et al. teach that the width of the implant body is 40mm, col. 5, lines 17-19. It would have been obvious to one of ordinary skill in the art to use a width of 40mm for the plates as taught by Boriani et al. in the baseplate of Paponneau as modified with Nishijima et al. such that the baseplates have a sufficient dimension to accommodate a lumbar region as taught by Boriani. Regarding claim 17 it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a depth having a range between 14-18mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Claims 1,5-7,10,11,15,18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over McKay (WO 99/29271) in view of Ray et al. (EP 369603). McKay shows (Fig. 33) apparatus for an intervertebral space having two baseplates **131,132**

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immovably coupled via a cylindrical trunk **133** extending there between. It can be seen at least one of the baseplates has a plurality of holes extending into the baseplate.

However, McKay does not explicitly state the holes extend entirely through such that they extend into the inward surface of the baseplate. It is noted that the holes are perpendicular to a plurality of surgical approach directions used to insert the baseplates.

Ray et al. teach (Fig. 1) to include holes **18** in the plates of an intervertebral implantable device such that the holes extend into the inward surface and through. Ray teaches the holes enable bone ingrowth to occur, col. 5, lines 13-17. It would have been obvious to one of ordinary skill in the art to modify the holes of the baseplate of McKay and to have them extend entirely through into the inward surface of the baseplate as taught by Ray et al. such that it ensures the structure is secured in the intervertebral space. Please note the intended use carries no weight in the absence of any distinguishing structure.

With respect to claims 6, 7 since the trunk has a smaller diameter it can be said a groove exists between the plates. Regarding claims 10, 11 any of the surgical approaches are fully capable of being used to insert the apparatus. With respect to claim 15, it can be seen the two baseplates have different width and depth dimensions as plate **131** is different than plate **132**.

Claims 16, 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over McKay (WO 99/29271) in view of Ray et al. (EP 369603) as applied to claim 15 above, and further in view of Boriani et al. (6159211). McKay as modified by Ray et al. is explained supra. However, McKay in view of Ray et al. do not explicitly disclose the width dimension in a range up to 40mm. Boriani et al. teach that the width of the implant

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body is 40mm, col. 5, lines 17-19. It would have been obvious to one of ordinary skill in the art to use a width of 40mm for the plates as taught by Boriani et al. in the baseplate of McKay as modified with Ray et al. such that the baseplates have a sufficient dimension to accommodate a lumbar region as taught by Boriani. Regarding claim 17 it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a depth having a range between 14-18mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M- F (9am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700
/Brian E Pellegrino/
Primary Examiner, Art Unit 3738